

REMARKS

This is in response to the Office Action mailed on September 15, 2005. In the Office Action, claims 1-35 were rejected. No amendments have been made to the claims. The present application includes claims 1-35.

The Office Action rejected claims 1-35 under 35 U.S.C. §103(a) as being unpatentable over Carlyle et al. International Publication No. WO 99/37337 (the Carlyle application) in view of U.S. Patent No. 6,124,131 (the Semenza patent) or Tsuzuki et al. (the Cancer Research article). The Office Action alleges that the Carlyle application teaches a medical device on which VEGF has been attached to promote population of the device with viable cells and other positive results. The Office Action further alleges that the Carlyle application teaches all the claimed devices in detail through the reference and also details means for attaching the peptide to the device in all of the methods Applicants claim. The Office Action further alleges that the Carlyle application teaches all of the claimed limitations except that the reference uses VEGF and does not teach using a VEGF stimulation compound. The Office Action then alleges that at the time that the invention was made, it would have been obvious of one of ordinary skill in the art to substitute a known VEGF stimulation compound for the VEGF used by the Carlyle application because such a compound would have caused the production of a desired compound VEGF.

The Office Action admits that the Carlyle application does not teach using HIF-1 $\alpha$  as the stimulator/agonist of VEGF. However, the Office Action alleges that it would have been obvious at the time the invention was made to use HIF-1 $\alpha$  in lieu of VEGF in the process disclosed in the Carlyle application or device disclosed in the Carlyle application because the Semenza

patent and Cancer Research Article teach that HIF-1 $\alpha$  is a known stimulator of VEGF.

Applicants respectfully disagree that claim 1 is made obvious by the Carlyle application in view of either the Semenza patent or the Cancer Research Article. Elements of claim 1 include a medical device comprising a stimulation compound associated with the medical device wherein the stimulation compounds stimulates production of VEGF, where the medical device is an implantable medical device, a catheter, a dressing or a surgical instrument.

There is no disclosure in any of the prior art references of a medical device having a stimulation compound associated therewith where the stimulation compounds stimulates production of VEGF.

Rather, the Carlyle application teaches the use of VEGF and VEGF-related compounds in association with prostheses to stimulate chemotaxis and cell growth (see p. 8, l. 4-14 of the Carlyle application, for example). The Carlyle application does not disclose or teach use of a stimulation compound associated with a medical device to stimulate growth factors. Further, the Carlyle application does not disclose a stimulation compound such as HIF-1  $\alpha$ , to stimulate production of VEGF.

Next, the Office Action alleges that the Semenza patent and the Cancer Research Article teach that HIF-1 $\alpha$  can be substitute for the VEGF disclosed in the Carlyle application to stimulate production of VEGF. Neither the Semenza patent nor the Cancer Research Article, either singly or in combination with the Carlyle application, teach or suggest associating a stimulation compound, such as HIF-1 $\alpha$ , with a medical device that stimulates production of VEGF as claimed in claim 1. Further, neither the Semenza patent nor the Cancer Research Article teaches using HIF-1 $\alpha$  as a stimulation compound for the production of VEGF to be associated with a medical device. Therefore, there is no teaching

or suggestion in either the Carlyle application, the Semenza patent or the Cancer Research article to combine the references to allege that claim 1 is obvious.

Further, the use of a stimulation compound provides advantages over a prosthesis associated with the growth factors themselves. As disclosed on page 16 of the Carlyle application, the binding of VEGF to glutaraldehyde cross linked tissues last for up to a month or longer when the tissue is in contact with the buffer solution. The Carlyle application teaches that the attachment of VEGF to the prosthesis will decline resulting in the reduction of VEGF concentration around the prosthesis over time.

In contrast, the association of the stimulation compound to the medical device can be gradually released into the fluids or tissues surrounding the medical device. (See p. 18, l. 8-10). Gradually releasing the stimulation compound allows for the concentration of VEGF around the medical device to be maintained over time. Therefore, the stimulation compound of the present invention can provide advantages in increasing the biocompatibility of the medical device over time when compared to directly binding VEGF to the medical device as disclosed in the Carlyle application.

Therefore, the present invention is not made obvious by the combination of the Carlyle application in view of the Semenza patent or the Cancer Research Article. Reconsideration and allowance of claim 1 are respectfully requested.

The Office Action also rejected claims 2-30 as being obvious over the Carlyle application in view of either the Semenza patent or the Cancer Research article. While Applicants do not acquiesce to the rejection of claims 2-30, Applicants believe that these rejections are moot in view of the remarks made in connection with independent claim 1. Since independent claim 1 is believed to be in allowable form, dependent claims 2-

30 which contain all of the element of claim 1, are also believed to be in allowable form. Reconsideration and allowance of claims 2-30 are respectfully requested.

The Office Action rejected independent claim 31 for the reasons stated with respect to independent claim 1. Applicants respectfully disagree that claim 31 is made obvious by the combination of the Carlyle application with either the Semenza patent or the Cancer Research article for the reasons stated regarding claim 1.

Elements of claim 1 include a method for producing a medical device comprising associating a stimulation compound with a biocompatible material to stimulate the production of growth factors. As previously stated with respect to independent claim 1, there is no disclosure in any of the cited references of associating a stimulation compound with a medical device to stimulate the production of the growth factor.

Rather, the Carlyle application discloses directly associating a growth factor with the medical device. There is no disclosure in the Carlyle application of associating a stimulation compound with the medical device to promote the production of growth factor.

Both the Semenza patent and the Cancer Research article disclose that HIF-1 $\alpha$  is a stimulator for the production of VEGF. However, there is no disclosure in either the Semenza patent or the Cancer Research article of using HIF-1 $\alpha$  as a stimulation compound on a medical device. Therefore, there is no teaching or suggestion in either the Carlyle application in combination with either the Semenza patent or the Cancer Research article for a method of producing a medical device by associating a stimulation compound to a biocompatible material for the production of a growth factor.

As such, claim 31 is not made obvious and is in allowable form. Reconsideration and allowance of claim 31 are respectfully requested.

Claims 32-35 were rejected for the reasons stated with respect to independent claim 1. While Applicants do not acquiesce to the particular rejections, the rejections are moot in light of the fact that independent claim 31 is believed to be in allowable form. Since independent claim 31 is in allowable form, claims 32-35 which depend from independent claim 31 and contain all of the elements of claim 31, are also in allowable form. Reconsideration and allowance of claims 32-35 are respectfully requested.

In view of the reasons provided above, it is believed that all depending claims are in condition for allowance. Applicants respectfully request favorable reconsideration and early allowance of all pending claims.

The Director is authorized to charge any fee deficiency required by this paper or credit any overpayment to Deposit Account No. 23-1123.

Respectfully submitted,

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